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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,656	02/11/2004	Rafail Zubok	532/2x3 (F-280 Cont II)	3382
27538	7590	06/24/2004	EXAMINER	
KAPLAN & GILMAN, L.L.P.			MILLER, CHERYL L	
900 ROUTE 9 NORTH			ART UNIT	PAPER NUMBER
WOODBIDGE, NJ 07095			3738	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/776,656	Applicant(s) ZUBOK ET AL.	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/11/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is a Markush type claim, and should contain the language, "selected from the group consisting of".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 12, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by William et al. (US 2004/0010316 A1). Referring to claims 1, 8, and 12, William discloses an apparatus (10) for replacing at least a portion of an intervertebral disc in a spinal column [0006] comprising a first member (12) having a first vertebral contact surface (16) for engagement with an endplate of a first vertebral bone in the spinal column, and having a first saddle shaped articulation surface (surface 60 of 18, saddle, being interpreted by it's broadest definition as being a ridge connecting to two higher elevations), and a second member (14) having a second vertebral contact surface (20) for engagement with an endplate of a second vertebral bone in the spinal column, and having a second saddle shaped articulation surface (surface 120 of 22, saddle, being interpreted by its broadest definition as being a ridge connecting two higher elevations), wherein an intervertebral disc space is defined substantially between the first and second

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endplates of the first and second vertebral bones, and the first (60) and second (120) articulation surfaces are sized and shaped to engage one another (fig.2, 40) when the first and second members are disposed in the intervertebral disc space to enable the first and second vertebral bones to articulate in at least one of flexion, extension and lateral bending, or to rotate relative one another through a range of angles without displacing the vertebral bones away from one another [0078].

Referring to claims 2-3, William discloses first (60) and second (120) articulation surfaces sized and shaped to define at least one of a first center of rotation for at least one of flexion and extension that is located outside the intervertebral disc space, and a second center of rotation for lateral bending that is located outside the intervertebral space (both centers of rotation will be located below the disc space, and will be located at different locations below the disc space, since the arcs of curvature are different, see figs.6,12, and may be symmetrical, or asymmetrical, [0071, 0076]). William discloses the centers of rotations located in different directions (both below the disc space, but one more proximal and one more distal).

Referring to claims 4-7, William discloses first (60) and second (120) articulation surfaces formed of from the materials claimed [0065].

Referring to claim 9, William discloses the articulation surfaces (60, 120) having point-to-point contact relative to one another when in at least some position of flexion, extension, lateral bending, and/or axial rotation [0078].

Referring to claim 14, William discloses the articulation surfaces sized and shaped to displace away the vertebral bones at rotation outside the range of angles (see figures).

Claims 1-12 and 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferree et al. (US 2004/0024462 A1). Referring to claims 1, 8, and 12, Ferree discloses an apparatus for replacing at least a portion of an intervertebral disc in a spinal column [0002] comprising a first member (top member in figs.3a-3b and 4a-4e) having a first vertebral contact surface (top surface) for engagement with an endplate of a first vertebral bone in the spinal column, and having a first saddle shaped articulation surface (bottom surface), and a second member (bottom member in figs.3a-3b and 4a-4e) having a second vertebral contact surface (bottom surface) for engagement with an endplate of a second vertebral bone in the spinal column, and having a

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second saddle shaped articulation surface (top surface), wherein an intervertebral disc space is defined substantially between the first and second endplates of the first and second vertebral bones, and the first and second articulation surfaces are sized and shaped to engage one another when the first and second members are disposed in the intervertebral disc space to enable the first and second vertebral bones to articulate in at least one of flexion, extension and lateral bending, or to rotate relative one another through a range of angles without displacing the vertebral bones away from one another [0007, 0024].

Referring to claims 2-3, Ferree discloses first and second articulation surfaces sized and shaped to define at least one of a first center of rotation for at least one of flexion and extension that is located outside the intervertebral disc space (above the disc space from the plane seen in fig.3a, 4d, 4e), and a second center of rotation for lateral bending that is located outside the intervertebral space (below the disc space from the plane seen in fig.3b, 4a). Ferree discloses the centers of rotations located in different directions.

Referring to claims 4-7, Ferree discloses first and second articulation surfaces formed of from the materials claimed [0008].

Referring to claim 9, Ferree discloses the articulation surfaces having point-to-point contact relative to one another when in at least some position of flexion, extension, lateral bending, and/or axial rotation [0007, 0024], see figures.

Referring to claims 10-11 and 15-17, Ferree discloses a first saddle shaped articulation surface (bottom surface of the top member in figures) defined by a concave arc (fig.3b, 4a), generally of radius A about a first axis substantially perpendicular to an anterior-posterior plane of the spinal column, and a convex arc (fig.3a, 4d, 4e), generally of radius B about a first axis substantially perpendicular to a lateral plane of the spinal column, a second saddle shaped articulation surface (top surface of bottom member in figures) defined by a convex arc (fig.3b, 4a), generally of radius C about a second axis substantially perpendicular to the anterior-posterior plane of the spinal column, and a concave arc (fig.3a, 4d, 4e), generally of radius D about a second axis substantially perpendicular to the lateral plane of the spinal column, and wherein the radius A of the concave arc is greater than the radius C of the convex arc and the radius D of the concave arc is greater than the radius B of the convex arc in order to permit axial

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rotation (inherently the concave surfaces must be larger than the convex surfaces, if movement is occurring, [0007, 0024]).

Referring to claim 14, Ferree discloses the articulation surfaces sized and shaped to displace away the vertebral bones at rotation outside the range of angles (see figures).

Claims 1-4 and 6-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Shelokov (USPN 6,039,763). Referring to claims 1, 8, and 12, Shelokov discloses an apparatus for replacing at least a portion of an intervertebral disc in a spinal column (col.1, lines 4-6) comprising a first member (1) having a first vertebral contact surface (2) for engagement with an endplate of a first vertebral bone in the spinal column, and having a first saddle shaped articulation surface (3), and a second member (10) having a second vertebral contact surface (11) for engagement with an endplate of a second vertebral bone in the spinal column, and having a second saddle shaped articulation surface (12), wherein an intervertebral disc space is defined substantially between the first and second endplates of the first and second vertebral bones (fig.7), and the first and second articulation surfaces are sized and shaped to engage one another when the first and second members are disposed in the intervertebral disc space to enable the first and second vertebral bones to articulate in at least one of flexion, extension and lateral bending, or to rotate relative one another through a range of angles without displacing the vertebral bones away from one another (col.4, lines 13-16; col.5, lines 46-51).

Referring to claims 2-3, Shelokov discloses first (3) and second (12) articulation surfaces sized and shaped to define at least one of a first center of rotation (23) for at least one of flexion and extension that is located outside the intervertebral disc space (fig.3a, 3b), and a second center of rotation for lateral bending that is located outside the intervertebral space (in fig.4a, 4b, the center of rotation about the concave portion of the top element and convex portion of the bottom element will be below the disc space). Shelokov discloses the centers of rotations located in different directions.

Referring to claims 4, 6, and 7, Shelokov discloses first and second articulation surfaces formed of from the materials claimed (col.10, lines 15-20).

Referring to claim 9, Shelokov discloses the articulation surfaces having point-to-point contact relative to one another when in at least some position of flexion, extension, lateral bending, and/or axial rotation (see figures; col.5, lines 46-51; col.4, lines 13-16).

Referring to claims 10-11 and 15-17, Shelokov discloses a first saddle shaped articulation surface (3) defined by a concave arc (arc extending between 4 and 5 in fig.1b), generally of radius A about a first axis substantially perpendicular to an anterior-posterior plane of the spinal column, and a convex arc (arc of 3 seen in fig.1a), generally of radius B about a first axis substantially perpendicular to a lateral plane of the spinal column, a second saddle shaped articulation surface (12) defined by a convex arc (arc of 12 seen in fig.2b), generally of radius C about a second axis substantially perpendicular to the anterior-posterior plane of the spinal column, and a concave arc (arc of 12 seen in fig.2a), generally of radius D about a second axis substantially perpendicular to the lateral plane of the spinal column, and wherein the radius A of the concave arc is greater than the radius C of the convex arc and the radius D of the concave arc is greater than the radius B of the convex arc in order to permit axial rotation (col.3, lines 66-67; col.5, lines 60-64; col.8, lines 39-42).

Referring to claims 13 and 14, Shelokov discloses the articulation surfaces sized and shaped to rotate the vertebral bones relative to one another plus/minus 3 degrees and displace away the vertebral bones at rotations outside this range (col.5, lines 46-52).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree et al. (US 2004/0024462 A1). Referring to claim 13, Ferree discloses an apparatus for replacing an intervertebral disc substantially as claimed [0002]. Ferree discloses articulation surfaces that allow a limited amount of rotation [0007], which is based on the size of the components,

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however are silent to mention the dimensions for such components and thus degree of rotation. It would have been an obvious matter of design choice to have dimensioned the members to allow a 3 degree rotation, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level or ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Referring to claim 18, Ferree discloses articulation surfaces defined by concave and convex arcs, each having a radii of curvature (seen in figures), however is silent to mention the specific value of the radii of curvatures. It would have been an obvious matter of design choice to have dimensioned the members to have the specific radii of curvatures claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level or ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shelokov (USPN 6,039,763). Referring to claim 5, Shelokov discloses articulation surfaces formed from metal (col.10, lines 15-20), however is silent to mention specific examples of metals used. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have articulation surfaces of cobalt, chromium, titanium, or stainless steel, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Referring to claim 18, Shelokov discloses articulation surfaces defined by concave and convex arcs (see figures), each having a radius of curvature, however is silent to mention the specific value of the radii of curvatures. It would have been an obvious matter of design choice to have dimensioned the members to have the specific radii of curvatures claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level or ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER